

JS 44 (Rev. 12/12)

MMB**CIVIL COVER SHEET***Under Seal 16 W. R. 86*

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

United States of America, et al.
EX. Rel. [Under Seal]

(b) County of Residence of First Listed Plaintiff _____
 (EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

[Under Seal]

County of Residence of First Listed Defendant _____
 (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Ryan Allen Hancock
William Williams and Davidson
1545 Walnut St, 24th Floor Philly PA 19103

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF |
|---|---------------------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 |
| Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input checked="" type="checkbox"/> 315 False Claims Act <input type="checkbox"/> 490 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify): _____
- ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

31 U.S.C. § 3730 (b)(2)
False Claims Act

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$ _____

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____

DOCKET NUMBER _____

APR 27 2016

DATE

4/27/16

SIGNATURE OF ATTORNEY OF RECORD

Mr. A. Hancock

S.T.

FOR OFFICE USE ONLY

RECEIPT # _____

AMOUNT _____

APPLYING IFP _____

JUDGE _____

MAG. JUDGE _____

MMB

UNITED STATES DISTRICT COURT

Under Seal

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Ex Del. [Under Seal] **16 1986**Address of Defendant: [Under Seal]Place of Accident, Incident or Transaction: United States
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☐No ☒

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?
Yes ☐ No ☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases
(Please specify) False Claims Act

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) _____

Ryan Allen Hancock
 I, _____, counsel of record do hereby certify:
 (Check Appropriate Category)

- ☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
- ☐ Relief other than monetary damages is sought.

DATE: 4/27/16 Ryan Allen Hancock
Attorney-at-Law

Attorney I.D.#

92590

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

APR 27 2016

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 4/27/16 Ryan Allen Hancock
Attorney-at-Law

Attorney I.D.#

92590

MMB

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIAUnder SealCASE MANAGEMENT TRACK DESIGNATION FORMUnited States of America, et al.,
Ex Rel. [Underseal]

CIVIL ACTION

16 1986

[Under Seal]

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ()

Date

4/27/16

Attorney-at-law

Ryan Allen Hancock

Attorney for

DeLator - ~~DeLator~~

Telephone

215 656-3679

FAX Number

E-Mail Address

rhancock@wardlaw.com

APR 27 2016

C.A. No.

16 1986

COMPLAINT

Defendant.

Attorneys for *Qui Tam* Plaintiff/Relator

UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, and the
STATES of CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, the DISTRICT
OF COLUMBIA, FLORIDA, GEORGIA,
HAWAII, ILLINOIS, INDIANA, IOWA,
LOUISIANA, MARYLAND,
MASSACHUSETTS, MICHIGAN,
MINNESOTA, MONTANA, NEVADA, NEW
HAMPSHIRE, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND, TENNESSEE,
TEXAS, VERMONT, VIRGINIA,
WASHINGTON, and DOE STATES 1–21, *ex rel.*
DORY FRAIN,

Plaintiffs,

vs.

MEDICREA USA CORPORATION,

Defendant.

C.A. No.

COMPLAINT FOR VIOLATIONS OF THE
FEDERAL FALSE CLAIMS ACT, 31 U.S.C.
§ 3729 *et seq.*; CALIFORNIA FALSE
CLAIMS ACT, Cal. Govt Code § 12650 *et*
seq.; CALIFORNIA INSURANCE FRAUDS
PREVENTION ACT [Cal. Ins. Code § 1871 *et*
seq.]; COLORADO MEDICAID FALSE
CLAIMS ACT [Colo. Rev. Stat. § 25.5-4-
303.5, *et seq.*]; CONNECTICUT FALSE
CLAIMS ACT, Conn. Publ. Law 09-05;
DELAWARE FALSE CLAIMS AND FALSE
REPORTING ACT, 6 Del. C. § 1201 *et seq.*;
DISTRICT OF COLUMBIA FALSE CLAIMS
ACT, D.C. Code Ann. § 2-308.13 *et seq.*;
FLORIDA FALSE CLAIMS ACT, Fla. Stat.
Ann. § 68.081 *et seq.*; GEORGIA FALSE
MEDICAID CLAIMS ACT, Ga. Code Ann.
§ 49-4-168 *et seq.*; HAWAII FALSE CLAIMS
ACT, Haw. Rev. Stat. § 661-21 *et seq.*;
ILLINOIS FALSE CLAIMS ACT, 740 Ill.
Comp.

Stat. § 175/1-8; ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT [740 Ill.
Comp. Stat. § 92]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION
ACT, Ind. Code § 5-11-5.5 *et seq.*; IOWA FALSE CLAIMS ACT, Iowa Code § 685.1 *et seq.*;
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, La. Rev. Stat. § 437
et seq.; MARYLAND FALSE HEALTH CLAIMS ACT, Md. HEALTH-GENERAL Code Ann.
§ 2-601 *et seq.*; MASSACHUSETTS FALSE CLAIMS ACT, Mass. Gen. Laws Ch. 12 § 5 *et*
seq.; MICHIGAN MEDICAID FALSE CLAIMS ACT, Mich. Comp. Laws § 400.601 *et seq.*;
MINNESOTA FALSE CLAIMS ACT, Minn. Stat. § 15C.01 *et seq.*; MONTANA FALSE
CLAIMS ACT, Mont. Code Ann. § 17-8-401 *et seq.*; NEVADA FALSE CLAIMS ACT, Nev.
Rev. Stat. Ann. § 357.010 *et seq.*; NEW HAMPSHIRE FALSE CLAIMS ACT, N.H. Rev. Stat.
Ann. § 167:61 *et seq.*; NEW JERSEY FALSE CLAIMS ACT, N.J. Stat. § 2A:32C-1 *et seq.*;
NEW MEXICO MEDICAID FALSE CLAIMS ACT and NEW MEXICO FRAUD AGAINST
TAXPAYERS ACT, N.M. Stat. Ann. § 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*;
NEW YORK FALSE CLAIMS ACT, N.Y. State Fin. § 187 *et seq.*; NORTH CAROLINA
FALSE CLAIMS ACT, N.C. Gen. Stat. § 1-605 *et seq.*; OKLAHOMA MEDICAID FALSE
CLAIMS ACT, 63 Okl. St. § 5053 *et seq.*; RHODE ISLAND FALSE CLAIMS ACT, R.I. Gen.
Laws § 9-1.1-1 *et seq.*; TENNESSEE MEDICAID FALSE CLAIMS ACT, Tenn. Code Ann. §§
71-5-181 *et seq.*; TEXAS MEDICAID FRAUD PREVENTION LAW, Tex. Hum. Res. Code
Ann. § 36.001 *et seq.*; VERMONT FALSE CLAIMS ACT, 32 V.S.A § 630-642 *et seq.*;
VIRGINIA FRAUD AGAINST TAXPAYERS ACT, Va. Code Ann. § 8.01-216.1 *et seq.*; and

WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT, Wash. Rev. Code § 74.66.005 *et seq.*

FILED IN CAMERA AND UNDER SEAL
JURY TRIAL DEMANDED

Qui tam plaintiff Dory Frain, on behalf of the United States, the States of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and Doe States 1–21 (collectively “the States”), for her Complaint against defendant MEDICREA USA Corp. (“Medicrea” or “defendant”), alleges as follows.

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent statements, records, and claims made and caused to be made by defendant and/or its agents, employees and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729–33, and the false claims acts of the States as set forth below.

2. Recovery on behalf of the States is sought for damages arising from Medicrea’s violations of the California False Claims Act, Cal. Govt Code § 12650 *et seq.*; California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*; the Connecticut False Claims Act, Conn. Publ. Law 09-05; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 *et seq.*; the District of Columbia False Claims Act, D.C. Code Ann. § 2-308.13 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1-8; the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92; the Indiana False Claims and Whistleblower

Protection Act, Ind. Code § 5-11-5.5 *et seq.*; Iowa False Claims Act, Iowa Code § 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 437 *et seq.*; the Maryland False Health Claims Act, Md. HEALTH-GENERAL Code Ann. § 2-601 *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12 § 5 *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61 *et seq.*; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. § 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Vermont False Claims Act, 32 V.S.A §§ 630-642 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*; and the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.005, *et seq.*

3. For years, Medicea has used a variety of illegal promotional practices to market and sell devices for the treatment of spinal pathologies (“spinal devices”). The illegal practices in which Medicea has engaged are varied and widespread and are integral to defendant’s marketing and sales activities.

4. Medicea’s products are used to treat diseases of the spine, including scoliosis and

a variety of disorders requiring spinal fusion, and the defendant markets spinal devices to patients in age groups ranging from young children to elderly adults.

5. Sales of spinal devices are the sole source of revenue for Medicea, which, along with its parent company based in France, had more than \$31 million in revenue in 2015. In the first quarter of 2016, sales in the United States have increased by 27% relative to the first quarter of 2015. The retail prices for Medicea's products vary significantly, but a typical spinal device sold by defendant costs several thousand dollars.

6. As more fully described in the body of this Complaint, Medicea knowingly provides kickbacks in the form of financial incentives, discounts, and other inducements to healthcare providers to gain their business, in contravention of federal law. In particular:

a. Medicea provides extensive entertainment and travel perks to physicians who are key opinion leaders ("KOLs") and purchasers of its spinal devices. Such perks include international travel, entertainment and meals.

b. Medicea gives discounts to particular physicians and hospitals in order to induce the purchase and use of certain of its spinal devices and engages in "tying," i.e., giving a discount on one product to induce the purchase of another.

c. Medicea specifically instructs sales staff, in writing, to seek approval from defendant's Chief Executive Officer, Pierre Olivier ("Mr. Olivier"), to offers physicians free case trials to induce providers to purchase Medicea's products.

d. Medicea provides discounts to certain "strategic hospitals" with the approval of Mr. Olivier and Colby McMillan, Vice President of Sales & Business/Product Development ("Mr. Colby"). In practice, these are hospitals where KOLs and Medicea consultants are employed.

e. Medicea enters into paid consulting agreements with physicians that purportedly require the surgeons to perform various tasks. Most of the services listed in the agreements, such as monthly teleconferences, never occur. Moreover, the consulting agreements specifically require that consultants “have and . . . maintain status as a participating provider in, and . . . accept payment under, the Medicare and Medical Assistance reimbursement programs.” Medicea recognizes that Medicare and Medicaid reimburse a significant portion of the costs of purchasing and using the company’s products, which are expensive and often targeted toward the geriatric population, and through this term, can ensure that its so-called consultants are participants in government healthcare programs.

7. In addition, as more fully described in this Complaint, Medicea engages in off-label promotion of several of its spinal devices in contravention of federal law. “Off-label promotion” refers to the promotion of a medical device for uses that have not been approved as safe and effective by the United States Food and Drug Administration (“FDA”). In particular:

a. In sales pitch slides for its UNiD spinal devices, Medicea claims that using its accompanying software will reduce the risk of rod breakage, despite the fact that there is no biomechanical data to support the claim.

b. Although the indications for use (“IFUs”) for its UNiD devices do not permit Medicea to engage in planning for surgery, defendant nevertheless promotes and provides a lab service that offers end-to-end surgical mapping and planning for surgeons who purchase its products.

c. Ten months before the FDA cleared the usage of lateral mass screws with Medicea’s PASS OCT system, a spinal device used to treat pathologies of the occipito-

cervical-thoracic region of the spine, Medicea's sales package contained numerous images showing the use of lateral mass screws with the product. Moreover, salespeople were recommending the implantation of lateral mass screws despite the lack of FDA approval.

d. Medicea sales materials advertised a curved counterhook for surgeons to use with its spinal device systems, despite the fact that the curved product was not cleared by the FDA. Additionally, Medicea salespeople told surgeons that they could bend defendant's straight hooks to mirror the curved hooks, despite the fact that the alterations were not cleared by the FDA and were not tested for their impact on the strength of the hooks.

8. Medicea's management has established and maintained a corporate environment and management structure that facilitates and encourages the illegal practices described above. One individual, Mr. Olivier, serves as the Chief Executive Officer, the head of compliance and the head of human resources. Additionally, rather than having a lawyer or independent compliance officer review marketing materials to ensure compliance with the products' FDA labels, officers within the sales department hold a primary oversight role. The lack of accountability and corporate governance allows Medicea to maintain a system of kickbacks and off-label promotion with no meaningful debate within the company, and certainly no reporting to government regulators when a problem is discovered.

9. The foregoing practices have cheated the federal and state governments out of funds that should not have been paid and unlawfully enriched Medicea. Every claim for reimbursement for a Medicea spinal device submitted to a government health care program that was induced by one or more of these unlawful promotional practices constitute a false and

fraudulent claim for payment under the federal and state False Claims Acts.

10. The federal False Claims Act (“FCA”) was originally enacted during the Civil War, and was substantially amended in 1986, 2009 and 2010. Congress enacted these amendments to enhance and modernize the government’s tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government’s behalf.

11. The FCA, 31 U.S.C. §§ 3729 *et. seq.*, provides that any person who presents or causes to be presented false or fraudulent claims for payment or approval to the United States Government; knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims; or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the federal government.

12. The FCA allows any person having information about false or fraudulent claims to bring an action on behalf of the government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to enable the United States to (a) conduct its own investigation without the defendant’s knowledge, and (b) determine whether to join the action.

13. Based on these provisions and the provisions of the State false claims act statutes, *Qui tam* plaintiff and relator Dory Frain seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which

Medicrea's misconduct has extended.

II. PARTIES

A. Plaintiffs

14. *Qui tam* plaintiff-relator Dory Frain ("Relator") is a resident of the Commonwealth of Pennsylvania. Relator was employed by Medicrea from July 2012 until February 2016. Relator held the position of Chief Training Officer. Among other duties, Ms. Frain had global training responsibilities for Medicrea employees and contractors and regularly developed new trainings as the state of the law and Medicrea's products evolved. Ms. Frain reported directly to the Chief Executive Officer of Medicrea USA Corp., Mr. Olivier. Ms. Frain introduced the first sales training curriculum in the history of Medicrea. Ms. Frain also served as the Medicrea liaison for surgeons on the use of products and treatment of complex spinal pathologies. Ms. Frain is a BSN and RN with significant experience in developing policies, procedures, and training around spine-related products.

15. The governmental plaintiffs in this lawsuit are the United States and the States of California, Colorado Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, the District of Columbia, and Doe States 1–21 (collectively "the States").

16. Plaintiffs Doe States 1–21 consist of the States that subsequent to the filing of this Complaint enact false claims act statutes that permit *qui tam* lawsuits, or whose previously enacted statutes become effective after the filing of this Complaint. Doe States 1–21 consist of the States of Alabama, Alaska, Arizona, Arkansas, Idaho, Kansas, Kentucky, Maine, Mississippi,

Missouri, Nebraska, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming.

B. Defendant

17. Defendant Medicea USA Corporation is a Foreign Business incorporated in the State of Delaware and the State of New York with its corporate headquarters in New York. Defendant is a wholly owned subsidiary of MEDICREA Group, based in Lyon, France. Medicea USA Corp. was founded in 2006, and the company promotes and sells its devices in this District and across the United States. The MEDICREA Group reported approximately \$31 million (€ 27.8 million) in revenue in the year ending December 31, 2015, a 15% increase over the previous year. Of these sales, an estimated 60% occurred in the United States, their “primary market.”

III. JURISDICTION AND VENUE

18. Jurisdiction is based on 28 U.S.C. § 1331, 28 U.S.C. §1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint. There has been no public disclosure of the allegations or transactions set forth in this Complaint. Moreover, even if such a public disclosure had occurred, this Court would retain jurisdiction over this matter because Relator is the original source of the facts and information hereinafter set forth.

19. This Court has personal jurisdiction over defendant, pursuant to 31 U.S.C. § 3732(a), because that section authorizes nationwide service of process and because defendant has minimum contacts with the United States. Moreover, the defendant can be found in, resides in, and/or transacts business in this judicial district.

20. Venue is proper, pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)–(c), because the defendant can be found in, resides in, and/or transacts business in this judicial district. In addition, statutory violations, as alleged herein, occurred in this judicial district.

IV. APPLICABLE LAW

A. FDA Regulation of Medical Devices

21. In 1976, Congress enacted the Medical Device Amendments (“MDA”), 21 U.S.C. § 360c, *et seq.*, to the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301, *et seq.*, in order to synchronize the FDA regulation of medical devices with that of pharmaceutical products, and “to provide for the safety and effectiveness of medical devices intended for human use.” Pub. L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). The MDA expanded the authority of the FDA to regulate medical devices, a business that has since grown exponentially into an approximately \$133 billion dollar industry in 2016, consisting of over 6,500 medical device companies. The Center for Devices and Radiological Health (“CDRH”) operates within the FDA to regulate medical devices.

22. Medical devices may not be introduced into the market until and unless the FDA has approved the device for commercial distribution. Three routes exist for manufacturers of devices to obtain FDA approval. Most commonly, manufacturers seek “premarket approval” (“PMA”) from the FDA, establishing, through extensive and lengthy review of data from clinical trials, bench and animal tests, “reasonable assurance” that the device is safe and effective for its intended use. 21 U.S.C. § 360e(d)(2), FDCA § 515(d)(2).

23. To obtain PMA for a given device, the FDA demands a complete report of all clinical and laboratory testing, a full statement of the components and design of the product, a description of the manufacturing process and quality controls, sample labeling instructions, and

other detailed information. 21 U.S.C. § 360e(c)(1). This rigorous process requires the FDA to spend months, and sometimes years reviewing and evaluating each such application, often in lengthy discussions with the manufacturer regarding safety and other concerns. For manufacturers like Medicea, the process is necessarily prolonged, rigorous, and costly, ensuring that the FDA releases for commercialization only those devices (and indications for use) that can safely be utilized among vulnerable patient populations.

24. There are two limited and exclusive exceptions to the PMA process with regard to manufacturers seeking to introduce their medical devices to consumers. First, a device can be sold if cleared by the FDA under the so-called 510(k) process, whereby the manufacturer can market and sell a device which is a “substantial equivalent” to a device already approved for the same use, where it certifies that the information submitted pursuant to the 510(k) process is “truthful and accurate.” 21 U.S.C. § 360; 21 C.F.R. § 807.87(k). The manufacturer must obtain a clearance letter from the FDA permitting it to market the device in question for indicated uses. Medicea has on numerous occasions availed itself of the 510(k) process.

25. Second, devices judged to reflect innovative technology may be marketed under a restricted “investigational device exemption,” or “IDE,” for purposes of conducting investigations of that device. 21 U.S.C. § 360j(g); 21 C.F.R. § 812.1. None of Medicea’s spinal devices at issue in this Complaint have been approved by the FDA under an IDE exception.

26. A medical device may not lawfully be marketed or promoted for a use not previously approved by the FDA under at least one of the three routes described above – the PMA process, the 510(k) process, or the IDE process.

27. A medical device is not approved *in general*. A medical device is only approved on the basis of its intended use, or approved “indication,” which must then be included in the

device's labeling. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5. If a manufacturer wishes to market a new, unapproved use for a device, it must first obtain FDA approval, through a "premarket notification submission" (through one of the routes explained above) so that its labeling is changed to indicate the limits of any FDA approval of such additional or substitute uses. 21 C.F.R. § 807.81(a)(3).

28. "Off-label" refers to the promotion or use of an approved medical device for any purpose, or in any manner, other than what is stated in the product's labeling (*i.e.*, what has been approved by the FDA as an "indication"). The term "labeling" under food and drug laws is given very broad meaning and includes all forms of communication and information disseminated by a device manufacturer.

29. Off-label promotion renders a medical device "misbranded." A medical device is deemed "misbranded," and its sale and promotion therefore unlawful, when it is promoted or otherwise marketed in a manner inconsistent with its approved FDA label. 21 U.S.C. § 331 and § 352.

30. The FDCA prohibits the "introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). Further, it prohibits "the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act . . . results in such article being adulterated or misbranded." 21 U.S.C. § 331(k).

31. Once a device is approved for a particular use, the FDA does not prohibit doctors from *using* that device for purposes different than those approved by the FDA. However, the manufacturer is prohibited from *promoting* any unapproved use.

32. The prohibition against off-label promotion protects patients and consumers by seeking to ensure that manufacturers do not promote their devices for uses other than those found

to be safe and effective by an independent and scientific governmental body – the FDA.

B. The Anti-Kickback Statute

33. The federal health care Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of a Congressional concern that payoffs to those who influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these often difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

34. The Anti-Kickback statute prohibits any person or entity from providing or accepting “any remuneration” to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The term “remuneration” in the Anti-Kickback statute is defined to include any item or service provided “for free or for other than fair market value.” 42 U.S.C. §1320a-7a(i)(6).

35. The statute prohibits a medical device company from offering to pay any remuneration, in cash or kind, directly or indirectly, if one of the purposes of the remuneration is to induce physicians or others to recommend or use the company’s products.

36. In May 2003, the Inspector General of the Department of Health & Human Services (“HHS”) released a formal guidance to pharmaceutical manufacturers, identifying several marketing practices that constitute “kickbacks and other illegal remuneration” infecting federal health care programs. *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003).

37. Although the guidance is intended for drug manufacturers, the principles it articulates apply equally to device manufacturers. The guidance states:

Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.

Id. at 23737.

38. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7b(b)(2)(B); 1320a-7.

39. Any person convicted under the Anti-Kickback statute must be excluded from the Federal Health Care Program (i.e., not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the Federal Health Care Program for a discretionary period, and may consider imposing administrative sanctions of \$25,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

40. A claim for payment that includes items or services resulting from a violation of the Anti-Kickback statute is a false claim within the meaning of the False Claims Act. *See* 42 U.S.C. § 1320a-7b, as amended by the Patient Protection and Affordable Care Act., Pub. L. No. 111-148, § 6402(f) (2010).

41. Compliance with the Anti-Kickback statute is a precondition to participation as a health care provider under Medicare, Medicaid, CHAMPUS-TRICARE, CHAMPVA, Federal

Health Benefit Program, and other federal and state health care programs. Either pursuant to provider agreements, claims forms, or other appropriate manner, physicians who participate in a federal or state health care program generally must certify that they have complied with applicable laws and regulations including the Anti-Kickback statute.

42. Thus compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from federal and state health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from public funds for the resulting claims.

C. The Stark Statute

43. In general, the Stark Statute, 42 U.S.C. § 1395nn, prohibits a physician from making referrals for certain "designated health services" payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship. The statute also prohibits the entity from billing Medicare for those referred services. The Centers for Medicare and Medicaid Services ("CMS") has promulgated regulations interpreting the Stark Statute. Accordingly, a claim for payment that is based on a violation of the Stark Statute constitutes a false claim under the FCA.

D. Reimbursement of Medical Devices Under Federal Health Care Programs

1. The Medicare Program

44. Medicare is a federal health care program serving approximately 55 million elderly and disabled Americans.

45. The Medicare program is administered by CMS on behalf of the Secretary of HHS (the "Secretary"). CMS contracts with so-called "fiscal intermediaries," typically private insurance companies, to act as agents of the Secretary in administering the Medicare program.

In conformity with federal law, these intermediaries review claims to determine whether they are appropriate for reimbursement.

46. Medicare “Part A,” 42 U.S.C. §§ 1395c-1395i, provides insurance for covered inpatient hospital and related services. Medicare “Part B,” 42 U.S.C. §§ 1395j-1395w, is a supplemental program insuring other items and services, such as out-patient hospital and physician services, supplies, and laboratory tests. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

47. As a condition of coverage, Medicare requires that services be “reasonable and necessary for the diagnosis or treatment of illness or injury.” 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(l).

48. Providers who wish to participate in the Medicare program must ensure that their services are provided “economically and only when, and to the extent, medically necessary.” 42 U.S.C. §1320c-5(a). Medicare will not pay for services that are not “medically necessary.”

49. A provider may be excluded from participation in the Medicare program if that provider bills Medicare for medically unnecessary items or services. *See* 42 CFR § 1003.102.

50. The medical necessity requirement applies not only to the performance of specific procedures but also to pharmaceuticals and medical devices provided to patients.

51. The CMS Intermediaries’ Manual provides, under “General Exclusions from Coverage,” that “[m]edical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary.... Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA.” *See* Inter. Manual § 3151.1.

52. Additionally, when an otherwise approved medical device is used in an unapproved, off-label manner, the use is considered investigational and experimental, and therefore non-reimbursable. 42 C.F.R. § 411.15(o). Also, “Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not ‘reasonable’ and ‘necessary’... or because it is excluded from coverage for other reasons.” 42 C.F.R. § 405.207.

53. Medicare Part B typically pays for durable medical equipment and outpatient services by paying 80% of the allowable charge. For physician services, Medicare uses reimbursement rates calculated and published annually by CMS, based on location of the provider, using Current Procedural Terminology (“CPT”) codes. Similar to DRGs in the hospital setting, CPT codes seek to assign standard levels of reimbursement to standard medical procedures based on the effort and expense normally associated with efficient administration of such care.

54. CPT code reimbursement can include a professional services component designed to compensate for services rendered by doctors or other qualified medical professionals (such as licensed nurse practitioners or physician assistants) and/or a technical component payment that is intended to reimburse costs associated with equipment and supplies needed to perform outpatient diagnostic or treatment procedures. Physicians must also certify that that claims and the underlying transactions comply with Medicare laws, regulations and program instructions including the Federal Anti-Kickback statute and the Stark statute.

2. Other Government Health Care Programs.

55. Medicaid is a public assistance program providing for payment of medical expenses for the poor and disabled. Funding for Medicaid is shared between the federal and state governments. For dual-eligible patients (those eligible for both Medicaid and Medicare),

Medicaid pays the deductible for Medicare patients.

56. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. §§ 1396, *et seq.*

57. In addition to Medicare and Medicaid, the federal government provides reimbursement, in whole or part, for approved medical devices under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE, CHAMPVA, and the Federal Employees Health Benefit Program.

58. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

59. In addition to the federal programs, the States provide a number of state-funded health care programs.

60. Although medical devices and associated procedures are generally eligible for reimbursement under these federal and state health care programs, claims induced by off-label promotion or anti-kickback violations are not eligible for program reimbursement.

V. BACKGROUND

A. Diseases of the Spine and Polyaxial Spine Systems

61. The bones, ligaments, discs, nerves, blood vessels and muscle attachments of the

spine serve critical functions. The spine protects the spinal cord, which the brain's primary communication pathway with the body. It also facilitates motion of the body as a central point for muscle attachments, and is essential to movement of the core of the body and the support of the skeleton during standing and walking.

62. The spine consists of five regions. In order of descent from the skull, the regions are: cervical, thoracic, lumbar, sacrum, and coccyx. The spinal column contains thirty-three vertebrae separated by discs that allow for motion and act as shock absorbers.

63. The vertebrae themselves consist of several parts: the vertebral body, located towards the front of a body; the vertebral arch, located towards the back of the body; and the pedicle, tubes of bone that connect the vertebral body to the arch. The pedicle is the portion of a vertebra into which screws can be surgically inserted to stabilize a diseased or weakened spine.

64. Two common diseases of the spine are degenerative disc disease and scoliosis. In the former, which typically occurs in older adults, the intervertebral discs deteriorate, causing pressure on the nerves and pain. In the latter, there is an unnatural curvature of the spine. Scoliosis is a progressive condition that can cause a variety of problems, including pain, inhibited lung expansion, and cosmetic deformities. Scoliosis may be present from birth, or may develop in adults due to severe degeneration of intervertebral discs and/or compromised bone quality.

65. Physicians have developed numerous surgical techniques to treat diseases of the spine. One technique is a discectomy, in which an intervertebral disc is removed and replaced with a cage, or spacer, relieving pressure on the patient's nerves. Another prevalent medical technique is fusion, in which a surgeon stabilizes the patient's spine by inserting metal hardware, such as screws, rods, and plates. New bone grows around the metal, and the affected vertebrae

are rendered immobile by virtue of the hardware.

66. All of Medicea's products are designed to provide internal fixation of the spine through the fusion technique.

67. In 2012, the United States market for products designed to surgically treat diseases of the spine was about \$7. Billion and the global market is expected to grow to about \$14.9 billion by 2019. Of that, pedicle screw spinal fusion systems of the type sold by Medicea comprised about \$5.8 billion.

B. The Medicea Spinal Devices at Issue in this Complaint

68. Medicea's founding business partners and clinicians created the polyaxial spine system ("PASS") in or about 1996 in France. The system was redesigned subsequently based on user feedback. The second generation PASS was called PASS MED. Medicea's PASS is now in its third generation, PASS LP, which uses low-profile pedicle screws. Many line extensions, i.e., variations on defendant's products, have been developed to include screws, rods, hooks, and other instruments designed to better address the needs of the surgeon.

69. In August 2012, defendant decided to carry only a subset of the products produced by its French parent company: the PASS LP pedicle screw system and LigaPASS – band connectors used in a spinal surgery known as posterior thoracolumbar fixation.

70. As Medicea grew – defendant reported a global 15% growth in 2015 – Medicea added more products developed in France to its inventory for sale in the United States, with the idea of entering additional market spaces. Currently, the products Medicea sells in the United States include:

- a. LigaPASS and its line extensions, which include three different connectors and two different styles of bands

b. PASS LP and its line extensions, which include:

- i. An iliac link and larger iliac screws for the region of the spine connected to the pelvis.
- ii. D-RODs, a spinal rod type which prevents slippage during scoliosis derotation surgery. D-RODs were created because Medicea's PASS LP Cylindrical rods allowed for the spine to slip during derotation.
- iii. Degenerative screws, which include shorter screw posts for surgery involving the lower back - the longer screw posts took more time to lock down during surgery. The shorter screws allowed for faster surgeries involving the lower back.
- iv. Ring rods, intended to decrease the time needed to conduct spinal surgery by restoring alignment of the spine in the sagittal plane, i.e., the plane that divides the body into left and right sides. The rods decreased surgery time because the product was easier to assemble as opposed to posted screw systems.
- v. UNiD rods, which are customized thoracolumbar rods cleared by the FDA in November 2014. These rods, used in spinal fusion, are part of a stated Medicea initiative to revolutionize the spinal surgery by manufacturing patient-specific, customized rods. The design rationale is based on data which show that sagittal alignment of the spine is the strongest predictor of patient outcomes. The UNiD rods and the accompanying spacers (known as UNiD ALIF cages), are custom-manufactured using a three-dimensional printer.

vi. Stand-alone hooks and curved counterhooks:

1. Hooks are used to affix rods to vertebrae. Stand-alone hooks are used alone, and do not require coupling in that they do not require being assembled to another hook, unlike the original PASS product. Medicea did not, however, design an instrument for placement of the stand-alone hooks, and instead learned through trial and error what techniques might allow implantation without undue difficulty. To date, there is no formal instrument, process or technique guide regarding safe implantation of stand-alone hooks.
2. Curved counterhooks are hooks bent to a specified radius of curvature for allegedly easier insertion. Defendant's sales management staff instructed sales representatives that they should tell surgeons to bend the stem of straight stand-alone hooks with a Kocher, i.e., surgical forceps. In fact, this was both very dangerous and off-label, as detailed further herein.

c. PASS OCT, a posterior cervical spine system which is used for fusion of the back of the neck when the cervical spine is unstable.

d. K-JAWS, a staple for anterior cervical fixation which "...allows insertion, impaction, and implant compression, after bone preparation." K-JAWS was based upon and used data from Medicea's C-JAWS product.

e. MANTA, a plastic spacer used in conjunction with the K-JAWS product. Spacers replace the disc removed during a discectomy and spinal fusion surgical procedure.

VI. MEDICREA'S UNLAWFUL PRACTICES

A. Medicrea Violates the Anti-Kickback Statute By Providing Health Care Professionals Financial Inducements to Refer, Recommend, or Arrange for the Purchase of Medicrea's Spinal Devices

71. As further described below, Medicrea employs a variety of methods to transfer value to surgeons and others to induce them to refer, recommend, or arrange for the purchase of Medicrea's spinal devices, in violation of the Anti-Kickback statute. The same conduct that violates the Anti-Kickback statute may also violate the Stark Statute when the recipient of the inducement has a financial relationship with Medicrea, such as through a consulting arrangement. As detailed below, Medicrea utilizes and has entered into numerous such consulting arrangements.

1. Medicrea Provides Unlawful Kickbacks to Surgeons in the Form of International Travel, Entertainment and Meals

72. Over the years, Medicrea and its French parent company have invited numerous U.S.-based surgeons to France, purportedly to observe surgeries using Medicrea products. In fact, surgeons spent far more time sightseeing, and defendant entertained them and their guests with sightseeing, wine tastings and lavish meals.

73. The most egregious example of such kickbacks occurred in September 2013 at a Scoliosis Research Society meeting. Medicrea sent approximately 100 invitations to surgeons and their spouses to attend an extravagant party in Lyon, France. Medicrea and its French parent company paid for the entertainment and for meals for both the surgeons and their spouses and families, in violation of the Anti-Kickback Law. Medicrea also paid the travel expenses for surgeons and their families, including: Dr. Evalina Burger and her husband; Dr. Afshin Aminian and his wife and children; Dr. Dennis Devito and his girlfriend; Dr. Andrew King; Dr. Frank Schwab; and Dr. Virginie LaFage. Each of these doctors had previously purchased three or four

of Medicea's spinal device systems, and the trip was intended to be a reward and inducement for their continued support.

74. Another example of kickbacks occurred in November 2014, at a North American Spine Society conference in San Francisco. During the conference, after business hours, Medicea hosted a wine-tasting for spine surgeons in the hope of inducing their purchase of Medicea products.

75. Medicea representatives also provide certain surgeons – generally paid consultants of the company – with tickets to sporting events to induce them to use Medicea's products or reward them for doing so.

76. Additionally, Medicea regularly pays for meals and entertainment for the spouses of surgeons, in violation of the Anti-Kickback law.

2. Medicea Gives Discounts to Select Surgeons and Hospitals and Ties Products to Induce the Purchase of Other Products

77. Medicea ties products and services and gives discounts – and even free products – in order to induce the purchase and use of certain spinal devices. Medicea's UNiD guide for salespeople contains a pricing page that specifically states that it will provide “up to 3 trials [of UNiD spinal rods] free with PASS LP, upon [Research & Development] approval.” Each UNiD rod costs between \$2,500 and \$3,500, and each surgery requires two rods for a value of up to \$7,000. Therefore, the provision of three free trials amounts to a total discount to healthcare providers of \$15,000 to \$21,000. The sole purpose of providing so many valuable trials in exchange for purchasing PASS LP is to induce providers to use Medicea's products.

78. Medicea also offers surgeons free case trials to use UNiD without purchasing PASS LP, “upon Medicea USA CEO approval.” In other words, Mr. Olivier, Chief Executive Officer of Medicea, will provide to surgeons UNiD devices, software and technical support

without charge. This is worth between \$5,000 and \$7,000 for a pair of UNiD rods, for which the surgeon does not pay Medicea. Because a standard spinal deformity surgery results in billings to insurance payors of \$20,000 to \$40,000, providing free UNiD rods and PASS LP systems allows the surgeon to see a larger profit. The goal of providing the free rods is to induce providers to use Medicea's products. Note that because UNiD rods are only cleared by the Food and Drug Administration (FDA) for use with the PASS LP screw system, Medicea's practice of providing UNiD rods to surgeons who do not purchase PASS LP is also a way to knowingly induce surgeons to use UNiD rods off-label in subsequent surgeries. The result is tens of thousands of dollars in additional revenue to Medicea for each such off-label use of UNiD rods.

3. Medicea Gives Thousands of Dollars in Free Products and Services to Select Surgeons to Induce the Purchase of Its Spinal Devices

79. Medicea provides other discounts to providers in order to induce the purchase of its products, including UNiD. Medicea provides written instructions to its sales representatives in UNiD sales guides stating that in pitching pricing of UNiD to potential purchasers, representatives should bear in mind that “[d]iscounts can be applied at some strategic hospitals” with the approval of Mr. Olivier and Mr. McMillan, Vice President of Sales & Business/Product Development. In practice, the strategic hospitals included are those at which key opinion leaders (“KOLs”) for Medicea products would be using the product. In addition to receiving rebates, these KOLs were often contracted consultants of Medicea.

4. Medicea Enters into Consulting Agreements with Surgeons for Work They Do Not Perform and Pays Them Bonuses to Induce the Purchase and Recommendation of Defendant's Products

80. Medicea enters into written consulting agreements with physicians that pay surgeons for services relating to the “evaluat[ion of] the clinical and biomedical principles”

associated with its spinal devices. Specifically, the agreements require that consultants:

- (1) “provide constructive feedback on instrumentation, surgical techniques and marketing and promotional materials and . . . be available to participate generally in MEDICREA sponsored events;”
- (2) “chair and assist in courses on topics related to the use, quality, or surgical implantation of [Medicrea spinal devices]” and provide other training services, including hosting attendees during surgeries performed using Medicrea spinal devices; and
- (3) “conduct evaluations and provide professional opinions,” including by authoring articles concerning Medicrea spinal devices for publication in “generally recognized professional journals.”

81. In practice, the physicians who enter into the consulting agreements with Medicrea are the only consistent users of Medicrea products, and they do not do some of the specific duties with which they are tasked pursuant to the consulting agreement, such as leading two annual think tanks and participating in twelve annual teleconferences. In fact such meetings simply do not occur. Significantly, the consulting agreements specifically require that consultants “have and . . . maintain status as a participating provider in, and . . . accept payment under, the Medicare and Medical Assistance reimbursement programs.” Medicrea recognizes that Medicare and Medicaid reimburse a significant portion of the costs of purchasing and using the company’s products, which are expensive and often targeted toward the pediatric and geriatric populations. By insisting on this term, Medicrea can ensure that its so-called consultants are participants in government healthcare programs.

82. Additionally, upon information and belief, Medicrea pays monetary bonuses to

these so-called consultants. In a conversation with Relator in 2015, David Steinbrecher, Manager of Logistics for Medicea, said that since “Dr. Schwab got his bonus,” he (Mr. Steinbrecher) expected to get a bonus, too. Mr. Steinbrecher did not elaborate on the basis for the bonus, but any such additional payment, particularly if tied to the purchase or use of Medicea products, is an unlawful inducement under the Anti-Kickback statute.

B. Medicea Has Engaged and Engages in Off-Label Promotion of Spinal Devices

83. Medicea makes numerous inaccurate and intentionally misleading claims in its promotional materials, and instructs its sales staff to do the same.

1. Medicea Promoted Its PASS Products for Pediatric Use Prior to Receiving FDA Clearance

84. From its founding in 2006, Medicea USA marketed its PASS LP system for use in pediatric patients. Marketing materials touted PASS LP as “the best system for de-rotation [of the spine],” but such claims were unsubstantiated. More importantly, PASS LP did not receive clearance from the FDA for use in pediatric patients until 2013, meaning that Medicea marketed the product off-label for seven years.

2. Medicea Promotes and Provides a Laboratory Service for Surgical Mapping and Planning for Its UNiD Product without FDA Clearance

85. Medicea’s sales pitch slides for its UNiD spinal device claim that designing rods with the UNiD plugin to Surgimap, a medical modeling software program, will “reduce the risk of rod breakage.” There is no biomechanical data to support this claim. In fact, Medicea conducted tests that showed that UNiD rods broke earlier than traditional rods. The paper cited in the marketing material in connection with Medicea’s claim simply presents data showing that spinal rods contoured with traditional bending instruments break earlier than pre-contoured rods

because the bending instrument creates notching in the rod. This paper, *Assessment of Symptomatic Rod Fracture after Posterior Instrumented Fusion for Adult Spinal Deformity*, Neurosurgery, 2012 Oct; 71(4):862-7, has nothing to do with Medicea UNiD products. Nevertheless, Medicea continues to make the unsubstantiated claim in promoting its product to surgeons.

3. Medicea Baselessly Claims in Sales Pitches that Its UNiD Plugin to Surgimap Software Reduces the Risk of Rod Breakage

86. Although Medicea acknowledges in its written instructions to salespeople that the indications for use (“IFUs”) approved by the FDA for its UNiD product “does not include planning by Medicea” for surgical installation of its rods. It nevertheless promotes its ability to use medical modeling software, Surgimap, to assist surgeons in planning for spinal surgery using its rods. In fact, its sales package provides the contact information for surgeons to “get started” by contacting the UNiD laboratory service, which was designed and implemented with the intent to provide end-to-end planning services. Prior to the launch of UNiD, Medicea hired an employee specifically to spearhead the UNiD lab, and two full-time Medicea employees are now dedicated to this service in the U.S. Medicea plans to grow the lab significantly based on an expected increase in UNiD sales and use. Surgeons rely on the Medicea lab to plan all cases, and the surgeon’s role in planning is essentially limited to an email signing off on what the lab has done. Because the lab services Medicea markets are not included in the IFUs, advertising them in conjunction with the UNiD product constitutes off-label promotion.

4. Medicea Promoted the Use of Lateral Mass Screws with Its Pass OCT System Prior to Receiving FDA Clearance

87. In a December 22, 2014, sales package for its PASS OCT system, a spinal device used to treat pathologies of the occipito-cervical-thoracic region, Medicea made a number of

off-label statements and depicted off-label uses for the product. Most notably, numerous images in the sales package showed lateral mass screws in the cervical section of the spine. Medicea also sent into the field spinal models that showed lateral mass screws. Medicea Sales Representatives also encouraged surgeons to provide feedback on the angulation of PASS OCT system for use with lateral mass screws. At the time, Medicea did not have FDA clearance to use lateral mass screws with PASS OCT, and ultimately did not receive clearance until October 2015, ten months after the sales package and models were in use by Medicea Sales Representatives in the field. Thus Medicea, through its Sales Representative were recommending the implantation of lateral mass screws despite the lack of FDA approval, thus engaging in off-label promotional practices.

5. Medicea Promoted the Alteration of Hooks Used in Its PASS Systems without FDA Clearance or Supporting Data

88. Medicea Sales Representatives engaged in off-label promotion by encouraging surgeons to bend straight counterhooks to facilitate assembly of its PASS systems during spinal surgeries. Such alterations were not approved in the technical guide filed with the FDA. Medicea had not conducted any tests to determine the impact that bending its straight counterhooks may have on the strength of the product – PASS systems. As Medicea knows well, bending metal inevitably weakens it, and any breakage of the counterhook during or after surgery could result in serious harm to a patient, including paralysis. Note that Medicea included a picture of a pre-bent counterhook in a 2014-15 product catalog, but defendant never received FDA clearance for it.

6. Medicea Promoted the Use of UNiD Rods without the PASS LP System for which They Were FDA-Cleared

89. UNiD rods are only cleared by the FDA for use with the PASS LP screw system.

However, as noted above, Medicea Sales Representatives, with the approval of Medicea management, provide UNiD rods to surgeons who do not purchase PASS LP.

90. While surgeons may decide to use UNiD with a Medicea competitor's system that accepts 5.5 – 6.0 millimeter rods, the FDA has not approved such a pairing, and Medicea may not market UNiD as compatible with a competitor's system.

91. The sales strategy of selectively approving the provision of free UNiD case trials without the purchase of PASS LP suggests that Medicea management are, in a targeted manner, knowingly promoting the off-label use of UNiD rods with other systems

7. Medicea Paid for Advertisements Quoting Doctors Advocating Off-Label Uses of LigaPASS

92. Medicea promotes its LigaPASS system in a variety of off-label ways. For example, Medicea has paid for cover advertisements in the widely circulated academic journal *Spine* that include quotes from a surgeon saying that he can use LigaPASS with any pedicle screw system on the market. In fact, while a surgeon can choose to use any pedicle screw system, LigaPASS is only cleared by the FDA for use with the PASS LP system. Quoting a surgeon in this manner in a paid advertisement is a transparent attempt by Medicea to circumvent the prohibition on promoting its products for off-label uses.

8. Medicea Provided UNiD Rods to Surgeons for Implantation Prior to FDA Clearance

93. Medicea engaged in an egregious act of off-label, pre-clearance promotion of its UNiD rods in the summer of 2014. Prior to FDA clearance of UNiD, defendant sent surgeons promotional packets, most of which included only a single UNiD rod. By sending single rods, Medicea avoided the possibility that a surgeon would implant the device prior to FDA clearance, since spinal fusions require a pair of rods. In the case of Dr. Frank Schwab (Dr.

Schwab”) at New York University, however, defendant sent a pair of UNiD rods at the doctor’s request so that he could implant them in a patient before FDA clearance. Individuals at the highest levels of Medicea management were aware of and approved the decision to send Dr. Schwab the rods, knowing that he intended to use them in a live patient. The practice not only constituted off-label promotion, but put potentially risked the patient’s life.

C. Medicea Has Established and Maintained a Corporate Culture That Fosters and Encourages Unlawful Conduct

1. Medicea’s Chief Executive Officer Also Leads Its Compliance and Human Resources Functions

94. One individual, Mr. Olivier, serves as Medicea’s Chief Executive Officer, the head of compliance, and the head of human resources. Mr. Olivier has no background in either compliance or human resources, and his triple role creates conflicts of interest. If an employee wishes to report a compliance issue, or retaliation for raising compliance, he or she must make that complaint to the same individual who exercises complete control over the business.

2. Sales Department Officers Review Marketing Materials for Compliance with FDA Labeling

95. Rather than having a lawyer or independent compliance officer review marketing materials to ensure compliance with the products’ FDA labels, officers within the sales department hold a primary oversight role. This creates an inherent tension. While the sales department is evaluated based on business generated, compliance with laws and regulations constrains the manner and means by which sales can be made. This lack of controls contributes, in part, to the off-label promotional practices detailed above.

3. Regulatory Agents Are Based in France, and Mr. Olivier Frequently Overrules Their Recommendations

96. Medicea’s only regulatory agents are located at the Medicea International

headquarters in France. While these agents are certified in regulatory affairs in France and the United State, Relator observed that they err on the side of leniency with respect to compliance with U.S. regulations.

97. Even if the regulatory affairs agents reach the correct conclusion with respect to compliance, Mr. Olivier can – and frequently does – override their assessments since he is both CEO and compliance officer.

98. Mr. Olivier also refuses to distribute to sales representatives any addenda to technique guides that accompany the approval of a line extension to an existing Medicea product. Without such information, Medicea Sales Representatives lack information that is critical to accurately describing and promoting a product to surgeons, which puts patients at risk.

VII. IMPACT ON PRIVATE INSURERS

99. The states of California and Illinois have enacted Insurance Fraud Prevention Acts that permit Relator to bring a *qui tam* action to recover for fraudulent claims submitted to *private* insurance companies in those states. *See* Counts III and XII below.

100. Medicea's practices alleged in this Complaint defraud private insurance companies in the same manner that the practices defraud the federal and state governments.

101. The practices alleged herein are systematic, nationwide practices that defraud private insurance companies that reimburse medical devices and related surgical services in every state where Medicea conducts business, including California and Illinois.

CLAIMS ON BEHALF OF THE UNITED STATES

Count I

Federal False Claims Act

31 U.S.C. §§ 3729(a)(1)(A), B), and (D)

102. Relator repeats and realleges each and every allegation contained in paragraphs 1

through 101 above as though fully set forth herein.

103. This is a claim for treble damages and penalties under the *False Claims Act*, 31 U.S.C. § 3729, *et seq.*, as amended.

104. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval under Medicaid, Medicare and various other government health care programs, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

105. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false and fraudulent claims paid or approved under Medicaid, Medicare and various other government health care programs, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

106. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the United States Government.

107. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

108. By reason of the defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

109. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by the defendant arising from their unlawful conduct as described herein.

CLAIMS ON BEHALF OF THE STATES

Count II
California False Claims Act
Cal Govt Code § 12651 et seq.

110. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 109 above as though fully set forth herein.

111. This is a claim for treble damages and penalties under the *California False Claims Act*.

112. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

113. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

114. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the California State Government.

115. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

116. By reason of the defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

117. Additionally, the California State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count III
California Insurance Frauds Prevention Act
California Insurance Code § 1871.7 et seq.

118. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 117 above as though fully set forth herein.

119. This is a claim for treble damages and penalties under the *California Insurance Frauds Prevention Act*, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as “the Act”). The Act provides for civil recoveries against persons who violate the provisions of the Act or the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between \$5,000 and \$10,000 for each such claim. Cal. Ins. Code §1871.7(b).

120. Subsection (e) of Cal. Ins. Code §1871.7 provides for a *qui tam* civil action in order to create incentives for private individuals who are aware of fraud against insurers to help disclose and prosecute the fraud. Cal. Ins. Code §1871.1(e). The *qui tam* provision was patterned after the Federal False Claims Act, 31 U.S.C. §§3729-32, and the California False Claims Act, Cal. Gov’t Code §§12650 et seq.

121. Subsection (b) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who violate the provisions of Penal Code sections 549 or 550. Section 550 of the Penal Code prohibits the following activities, among others:

(a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:

* * * * *

(5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.

(6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.

* * * * *

(b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:

(1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

(2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

(3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

122. By virtue of the acts described in this Complaint, the defendant knowingly presented or caused to be presented, false or fraudulent claims for health care benefits, in violation of Penal Code §550(a).

123. Each claim for reimbursement that was a result of the defendant's illegal practices represents a false or fraudulent record or statement, and a false or fraudulent claim for payment.

124. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by the defendant, paid and continue to pay the claims that would not be paid but for the defendant's unlawful conduct.

125. The California State Government is entitled to receive three times the amount of each claim for compensation submitted in violation of Cal. Ins. Code §1871.7. Additionally, the California State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count IV
Colorado False Claims Act
Colo. Rev. Stat. § 25.5-4-303.5, et seq.

126. Relator repeats and realleges each and every allegation contained in paragraphs 1

through 125 above as though fully set forth herein.

127. This is a claim for treble damages and penalties under the *Colorado False Claims Act*.

128. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

129. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

130. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Colorado State Government.

131. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

132. By reason of the defendant's acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

133. Additionally, the Colorado State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count V
Connecticut False Claims Act
Conn. Publ Law 09-05 et seq.

134. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 133 above as though fully set forth herein.

135. This is a claim for treble damages and penalties under the *Connecticut False Claims and Reporting Act*.

136. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

137. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

138. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Connecticut State Government.

139. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

140. By reason of the defendant's acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

141. Additionally, the Connecticut State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count VI
Delaware False Claims And Reporting Act
6 Del C. § 1201 et seq.

142. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 141 above as though fully set forth herein.

143. This is a claim for treble damages and penalties under the *Delaware False Claims And Reporting Act*.

144. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

145. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

146. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Delaware State Government.

147. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

148. By reason of the defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

149. Additionally, the Delaware State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count VII
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.13 et seq.

150. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 149 above as though fully set forth herein.

151. This is a claim for treble damages and penalties under the *District of Columbia*

False Claims Act.

152. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

153. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

154. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the District of Columbia Government.

155. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's defective laboratory tests, unnecessary treatments and surgeries, and/or illegal inducements and business practices.

156. By reason of the defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

157. The District of Columbia is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by the defendant.

Count VIII
Florida False Claims Act
Fla. Stat. Ann. § 68.082 et seq.

158. Relator repeats and realleges each and every allegation contained in paragraphs 1

through 157 above as though fully set forth herein.

159. This is a claim for treble damages and penalties under the *Florida False Claims Act*.

160. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

161. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

162. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Florida State Government.

163. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

164. By reason of the defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

165. Additionally, the Florida State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count IX
Georgia False Medicaid Claims Act
Ga. Code Ann. § 49-4-168 et seq.

166. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 165 above as though fully set forth herein.

167. This is a claim for treble damages and penalties under the *Georgia False Claims Act*.

168. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

169. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

170. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Georgia State Government.

171. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

172. By reason of the defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

173. Additionally, the Georgia State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count X
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21 et seq.

174. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 173 above as though fully set forth herein.

175. This is a claim for treble damages and penalties under the *Hawaii False Claims*

Act.

176. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

177. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

178. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Hawaii State Government.

179. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

180. By reason of the defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

181. Additionally, the Hawaii State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XI
Illinois False Claims Act
740 Ill. Comp. Stat. § 175 et seq.

182. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 181 above as though fully set forth herein.

183. This is a claim for treble damages and penalties under *the Illinois False Claims Act*.

184. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

185. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

186. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Illinois State Government.

187. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

188. By reason of the defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

189. Additionally, the Illinois State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XII
Illinois Insurance Claims Frauds Prevention Act
740 Ill. Comp. Stat. §92 et seq.

190. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 189 above as though fully set forth herein.

191. This is a claim for treble damages and penalties under the *Illinois Insurance Claims Fraud Prevention Act*, 740 Ill. Comp. Stat. §92.

192. Subsection 5(b) of the *Illinois Insurance Claims Fraud Prevention Act* provides:

A person who violates any provision of this Act or Article 46 of the Criminal Code of 1961 shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than \$5,000 nor more than \$10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.

193. Article 46 of the Illinois Criminal Code, referenced in the above-quoted section, provides criminal penalties for any person who commits the offense of insurance fraud, defined in the statute as follows:

(a) A person commits the offense of insurance fraud when she or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company

720 Ill. Comp. Stat. §5/46-1(a).

194. Subsection 15(a) of the *Illinois Insurance Claims Fraud Prevention Act* provides for a *qui tam* civil action in order to create incentives for private individuals to prosecute violations of the statute. Subsection 15(a) provides: “An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State.” 740 Ill. Comp. Stat. §92/15(a).

195. By virtue of the conduct described in this Complaint, the defendant committed the following acts, or aided and abetted the commission of the following acts, in violation of the *Illinois Insurance Claims Fraud Prevention Act*: knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat. §92/5(b) and 720 Ill. Comp. Stat. §5/46-1(a).

196. As a result of such conduct, the defendant has received illegal profits to which it

was not entitled, at the expense of insurers and at the expense of the People of the State of Illinois, in substantial amount to be determined at trial.

197. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by defendant in violation of 740 Ill. Comp. Stat. §92. Additionally, the Illinois State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XIII
Indiana False Claims And Whistleblower Protection Act
IC 5-11-5.5 et seq.

198. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 197 above as though fully set forth herein.

199. This is a claim for treble damages and penalties under the *Indiana False Claims and Whistleblower Protection Act*.

200. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

201. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

202. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Indiana State Government.

203. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid

and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

204. By reason of the defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

205. Additionally, the Indiana State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XIV
Iowa False Claims Act
Iowa Code § 685.1 et seq.

206. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 205 above as though fully set forth herein.

207. This is a claim for treble damages and penalties under the *Iowa False Claims Act*.

208. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

209. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Iowa State Government to approve and pay such false and fraudulent claims.

210. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Iowa State Government.

211. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

212. By reason of the defendant's acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

213. Additionally, the Iowa State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XV
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 437 et seq.

214. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 213 above as though fully set forth herein.

215. This is a claim for treble damages and penalties under the *Louisiana Medical Assistance Programs Integrity Law*.

216. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

217. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

218. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Louisiana State Government.

219. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

220. By reason of the defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

221. Additionally, the Louisiana State Government is entitled to the maximum penalty

of \$11,000 for each and every violation alleged herein.

Count XVI
Maryland False Health Claims Act
Md. HEALTH-GENERAL Code Ann. § 2-601, et seq.

222. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 221 above as though fully set forth herein.

223. This is a claim for treble damages and penalties under the *Maryland False Health Claims Act*.

224. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

225. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

226. By virtue of the acts described above, defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Maryland State Government.

227. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

228. By reason of the defendant's acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

229. Additionally, the Maryland State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XVII
Massachusetts False Claims Law
Mass. Gen. Laws Ch. 12 § 5B et seq.

230. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 229 above as though fully set forth herein.

231. This is a claim for treble damages and penalties under the *Massachusetts False Claims Act*.

232. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

233. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

234. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Massachusetts State Government.

235. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

236. By reason of the defendant's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

237. Additionally, the Massachusetts State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XVIII
Michigan Medicaid False Claims Act
Mich. Comp. Laws. § 400.601 et seq.

238. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 237 above as though fully set forth herein.

239. This is a claim for treble damages and penalties under the *Michigan Medicaid False Claims Act*.

240. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

241. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

242. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Michigan State Government.

243. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

244. By reason of the defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

245. Additionally, the Michigan State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XIX
Minnesota False Claims Act
Minn. Stat. § 15C.01 et seq.

246. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 245 above as though fully set forth herein.

247. This is a claim for treble damages and penalties under the *Minnesota False Claims Act*.

248. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

249. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

250. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Minnesota State Government.

251. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

252. By reason of the defendant's acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

253. Additionally, the Minnesota State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XX
Montana False Claims Act
Mont. Code Ann. § 17-8-401 et seq.

254. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 253 above as though fully set forth herein.

255. This is a claim for treble damages and penalties under the *Montana False Claims Act*.

256. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

257. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

258. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Montana State Government.

259. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

260. By reason of the defendant's acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

261. Additionally, the Montana State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XXI
Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040 et seq.

262. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 261 above as though fully set forth herein.

263. This is a claim for treble damages and penalties under the *Nevada False Claims Act*.

264. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

265. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

266. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Nevada State Government.

267. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

268. By reason of the defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

269. Additionally, the Nevada State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XXII
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b(I)

270. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 269 above as though fully set forth herein.

271. This is a claim for treble damages and penalties under the *New Hampshire False Claims Act*.

272. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

273. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

274. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the New Hampshire State Government.

275. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

276. By reason of the defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

277. Additionally, the New Hampshire State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XXIII
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1

278. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 277 above as though fully set forth herein.

279. This is a claim for treble damages and penalties under the *New Jersey False Claims Act*.

280. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

281. By virtue of the acts described above, defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

282. By virtue of the acts described above, defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the New Jersey State Government.

283. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

284. By reason of the defendant's acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

285. Additionally, the New Jersey State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XXIV
New Mexico Medicaid False Claims Act, N.M.
Stat. Ann. § 27-14-1 et seq. and New Mexico
Fraud Against Taxpayers Act, N.M. Stat. Ann.
§ 44-9-1 et seq.

286. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 285 above as though fully set forth herein.

287. This is a claim for treble damages and penalties under the *New Mexico Medicaid False Claims Act* and the *New Mexico Fraud Against Taxpayers Act*.

288. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

289. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

290. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the New Mexico State Government.

291. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

292. By reason of the defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

293. Additionally, the New Mexico State Government is entitled to the maximum civil

penalty of \$10,000 for each and every violation alleged herein.

Count XXV
New York False Claims Act
N.Y. State Fin. § 187 et seq.

294. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 293 above as though fully set forth herein.

295. This is a claim for treble damages and penalties under the *New York False Claims Act*.

296. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

297. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

298. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the New York State Government.

299. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

300. By reason of the defendant's acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

301. Additionally, the New York State Government is entitled to the maximum penalty

of \$12,000 for each and every violation alleged herein.

Count XXVI
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 et seq.

302. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 301 above as though fully set forth herein.

303. This is a claim for treble damages and penalties under the *North Carolina False Claims Act*.

304. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

305. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

306. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the North Carolina State Government.

307. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

308. By reason of the defendant's acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

309. Additionally, the North Carolina State Government is entitled to the maximum

penalty of \$11,000 for each and every violation alleged herein.

Count XXVII
Oklahoma Medicaid False Claims Act
63 Okl. St. § 5053 et seq.

310. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 309 above as though fully set forth herein.

311. This is a claim for treble damages and penalties under the *Oklahoma Medicaid False Claims Act*.

312. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

313. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

314. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Oklahoma State Government.

315. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

316. By reason of the defendant's acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

317. Additionally, the Oklahoma State Government is entitled to the maximum civil

penalty of \$10,000 for each and every violation alleged herein.

Count XXVIII
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 et seq.

318. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 317 above as though fully set forth herein.

319. This is a claim for treble damages and penalties under the *Rhode Island False Claims Act*.

320. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

321. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

322. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Rhode Island State Government.

323. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

324. By reason of the defendant's acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

325. Additionally, the Rhode Island State Government is entitled to civil penalties of

entitled to the maximum civil penalty of \$11,000 for each and every violation alleged herein.

Count XXIX
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)

326. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 325 above as though fully set forth herein.

327. This is a claim for treble damages and penalties under the *Tennessee Medicaid False Claims Act*.

328. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

329. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

330. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Tennessee State Government.

331. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

332. By reason of the defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

333. Additionally, the Tennessee State Government is entitled to the maximum penalty

of \$10,000 for each and every violation alleged herein.

Count XXX
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002 et seq.

334. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 333 above as though fully set forth herein.

335. This is a claim for treble damages and penalties under the *Texas Medicaid Fraud Prevention Law*.

336. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

337. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

338. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Texas State Government.

339. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

340. By reason of the defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

341. Additionally, the Texas State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XXXI
Vermont False Claims Act
32 V.S.A. § 630 et seq.

342. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 341 above as though fully set forth herein.

343. This is a claim for treble damages and penalties under the *Vermont False Claims Act*.

344. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Vermont State Government for payment or approval.

345. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Vermont State Government to approve and pay such false and fraudulent claims.

346. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Vermont State Government.

347. The Vermont State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

348. By reason of the defendant's acts, the State of Vermont has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

349. Additionally, the Vermont State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XXXII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(a)

350. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 349 above as though fully set forth herein.

351. This is a claim for treble damages and penalties under the *Virginia Fraud Against Taxpayers Act*.

352. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

353. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

354. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Virginia State Government.

355. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

356. By reason of the defendant's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

357. Additionally, the Virginia State Government is entitled to the maximum penalty of \$10,000 for each and every violation alleged herein.

Count XXXIII

Washington Medicaid Fraud False Claims Act
Wash. Rev. Code § 74.66.005, et seq.

358. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 357 above as though fully set forth herein.

359. This is a claim for treble damages and penalties under the *Washington Medicaid Fraud False Claims Act*.

360. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

361. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

362. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the Washington State Government.

363. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for the defendant's unlawful conduct.

364. By reason of the defendant's acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

365. Additionally, the Washington State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

Count XXXIV
Doe States' False Claims Acts That Have Not
Been Enacted or Are Not Effective at the Time of Filing

366. Relator repeats and realleges each and every allegation contained in paragraphs 1 through 365 above as though fully set forth herein.

367. This is a claim for treble damages and penalties against defendant under State False Claims Acts that are enacted subsequent to the filing of this Complaint, and which permit *qui tam* suits. The States that may enact False Claims Acts are: Alabama, Alaska, Arizona, Arkansas, Idaho, Kansas, Kentucky, Maine, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming.

368. By virtue of the acts described above, the defendant knowingly presented or caused to be presented, false or fraudulent claims to each of the States listed above.

369. By virtue of the acts described above, the defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the States listed above to approve and pay such false and fraudulent claims.

370. By virtue of the acts described above, the defendant knowingly and improperly avoided or decreased an obligation to transmit money or property to the States listed above.

371. The State Governments of each of the States listed above, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the defendant, paid and continues to pay the claims that would not be paid but for defendant's unlawful conduct.

372. By reason of the defendant's acts, the States listed above have been damaged and continue to be damaged in substantial amounts to be determined at trial.

373. The State Governments of each of the States listed above are entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendant.

Prayer

WHEREFORE, Relator prays for judgment against the defendant as follows:

374. that defendant cease and desist from violating 31 U.S.C. § 3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

375. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained because of defendant's actions, plus a civil penalty of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. § 3729;

376. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of California has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Cal. Govt. Code § 12651(a);

377. that this Court enter judgment against defendant in an amount equal to three times the amount of any fraudulent insurance claims in California and fines of the maximum penalty of \$10,000 for each violation of the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7 *et seq.*;

378. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Colorado has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*;

379. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendant's actions,

plus a civil penalty of \$11,000 for each violation of Conn. Pub. Law 09-05;

380. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of 6 Del. C. § 1201(a);

381. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of D.C. Code Ann. § 1-1188.14(a);

382. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Fla. Stat. Ann. § 68.082(2);

383. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Georgia Code Ann. § 49-4-168;

384. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Haw. Rev. Stat. § 661-21(a);

385. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

386. that this Court enter judgment against defendant in an amount equal to three times the amount of each claim for compensation submitted by defendant in violation of 740 Ill. Comp. Stat. § 92, plus a civil penalty of \$10,000 for each violation of 740 Ill. Comp. Stat. § 92;

387. that this Court enter judgment against defendant in an amount equal to three times

the amount of damages the State of Indiana has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Ind. Code § 5-11-5.5 *et seq.*;

388. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Iowa has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of the Iowa False Claims Act, Iowa Code § 685.1 *et seq.*;

389. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of La. Rev. Stat. § 437 *et seq.*;

390. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Maryland has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of Md. HEALTH-GENERAL Code Ann. § 2-601 *et seq.*;

391. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Mass. Gen. L. Ch. 12 § 5B *et seq.*;

392. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of Mich. Comp. Laws § 400.601 *et seq.*;

393. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Minnesota has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Minn. Stat. § 15C.01 *et seq.*;

394. that this Court enter judgment against defendant in an amount equal to three times

the amount of damages the State of Montana has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Mont. Code Ann. § 17-8-401 *et seq.*;

395. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1);

396. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I);

397. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of N.J. Stat. § 2A:32C-1 *et seq.*;

398. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of N.M. Stat. Ann. § 27-14-4 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*;

399. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of New York has sustained because of defendant's actions, plus a civil penalty of \$12,000 for each violation of N.Y. State Fin. § 187 *et seq.*;

400. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of North Carolina has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of N.C. Gen. Stat. § 1-605 *et seq.*;

401. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendant's actions, plus

a civil penalty of \$10,000 for each violation of 63 Okla. St. § 5053 *et seq.*;

402. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of R.I. Gen. Laws § 9-1.1-1 *et seq.*;

403. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of Tenn. Code Ann. § 71-5-182(a)(1);

404. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

405. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Vermont has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of 32 V.S.A. § 630 *et seq.*;

406. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendant's actions, plus a civil penalty of \$10,000 for each violation of Va. Code Ann. § 8.01-216.3(a);

407. that this Court enter judgment against defendant in an amount equal to three times the amount of damages the State of Washington has sustained because of defendant's actions, plus a civil penalty of \$11,000 for each violation of Wash. Rev. Code § 74.66.005, *et seq.*;

408. that Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

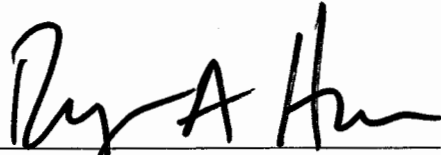
409. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

410. that Relator recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: April 27, 2016



Ryan Allen Hancock
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